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09/518,165	03/01/2000	Vladimir Andrei Koulchin		4746

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,165	KOULCHIN ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1, 2, 12-14, 22-52 is/are pending in the application.

4a) Of the above claim(s) 1, 2, 12-14 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed January 16, 2003 has been entered. Claims 22-34, 36, 43, 45, 48 and 50 have been amended. Claims 22-52 are under consideration in the office action.

Drawings

2. The corrected or substitute drawings were received on December 3, 2002. These drawings are acceptable.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 22-52 of this application.

Applicant argues that since the assays of the prior art led to recognition of the instant method and the broad generic concept is described in this application, then priority should be granted.

As per section 608.01(p) applications obviously failing to disclose an invention with the clarity required are discussed in MPEP § 702.01. A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date in order to obtain priority. In re Glass, 492 F.2d 1228, 181

USPQ 31(CCPA 1974). While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications or be found ☚ adequately supportive of priority claims.

None of the parent applications, for which priority is claimed 09/139,720, 09/156,486, 09/397,110 and 09/458,998 teach a method for detecting both gram-negative and gram-positive bacteria and associated devices. The specification by incorporation by reference recites individual aspects of each application, i.e., using essentially free carbohydrate antigens from particular species such as *Legionella* and *S. pnuemoniae*, however there is no teaching of a method wherein both gram-negative and gram-positive bacteria are assayed for. There was no conception of a method to detect the presence or concentration of any bacterial species, but rather to only detect specific bacterial species. Thus, priority cannot be granted to 09/139,720, 09/156,486,

09/397,110 and 09/458,998 since what is now claimed, has not been previously recited in the other applications.

Thus applicants' argument that the prior applications teach segments of generic concepts is not adequate to claim priority.

Specification

4. The abstract of the disclosure is objected to because the abstract refers to antigen-specific antibodies "oaf" enhanced sensitivity. Correction is required. See MPEP § 608.01(b).

Withdrawal of Objections and Rejections

5. The objections to claims 22-52 are withdrawn in view of applicants' amendments.

Response to Arguments

Applicant's arguments filed January 16, 2003 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The enablement rejection of claims 22-52 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The rejection was on the grounds that claim 22 is drawn to a method for detecting the presence of a carbohydrate antigen while claim 43 is drawn to an ICT device, obtaining a culture of a known bacterial species, coupling a spacer molecules to the essentially protein-free carbohydrate antigen, passing antibodies to produce purified carbohydrate antigen specific antibodies and conducting an assay. However the instant specification fails to provide any experiments that show the combination of purifying the carbohydrate antigen and conducting an assay as one method for detecting the presence of a carbohydrate antigen.

The instant specification teaches, starting at page 14, [redacted] separate steps for the purification of carbohydrate antigen of *Haemophilus influenzae* in example 2, preparation of affinity columns in example 3; purification of *H. influenzae* antibodies in example 4 and ICT assay for *Haemophilus influenzae* type b in example 5. The art purification is highly unpredictable and the instant specification fails to provide any information that any bacterial carbohydrate antigens could be purified and detected in the same claimed manner. There is no teaching of a method for detection that encompasses combining all the separate examples into one hybrid method. Moreover, there appears to be no conception of a method for detecting the presence of a carbohydrate antigen characteristic of at least one species or serogroup of a species of

bacteria, i.e., both gram negative and gram positive bacteria in one method using one purification procedure for any type of bacteria.

Applicant argues that the reference to Critical Synergy: The Biotechnology Industry and Intellectual Property Protection, Presentation of the intellectual Property Committee of the Biotechnology Industry Organization at the October 17, 1994, Hearing of the U.S. Patent and trademark Office, San Diego, CA, published by the Biotechnology Industry Organization, Washington, D.C. pages 100-107 was taken out of context because is was geared to specific areas of technology, which applicant deems, without any evidence to be non-inclusive of immunoassays, antigens and antibodies. Applicants' inability to obtain the entire document is unfortunate despite adequate reference being made and supplied by the examiner.

However, the issue is that applicants' specification is merely a general outline of purifying carbohydrate antigens and elucidating antibodies that bind and that there is no purification guidance specific for different types of bacteria. For instance, the specification at page 14 teaches different purification of carbohydrate antigen steps, including an incubation step, sonication step, repeated precipitation and centrifugation steps, lyophilization, subjected to Lowry assay for proteins and tested for carbohydrate by phenol-sulfuric acid method. It is well known in the art that specific bacterial species require specific extraction methods, yet the claims do not take this into consideration and generically claim a method of detection. The instant claims do not recite any of these necessary and specific method steps necessary to detect these crude carbohydrate antigens of any type of bacteria. There is [redacted] no support in the

specification for obtaining an essentially protein-free carbohydrate antigen in the manner claimed for any type of bacterial species. Furthermore, the claims are not enabled for conducting an assay by contacting liquid sample with a detection agent which essentially comprises labeled purified antigen-specific antibodies. Currently the claims do not require a particular type of bacteria; and in view of the method for detection of any type of bacteria, the specification fails to teach how to produce a purified antigen specific antibody that binds to an essentially protein free carbohydrate bacterial antigen.

Applicant questions how the hybrid method relates to the patentability and that the examples are broken up to increase clarity. However it is the examiner's position that since there is no hybrid method which encompasses the broad generic claims, yet such a method is necessary in order to achieve the functional limitation of an essentially protein-free carbohydrate antigen and purified antigen specific antibodies. The disclosure needs to teach purification procedures specific to individual species of gram negative and gram positive bacteria, or prove that any bacteria can be purified by the same generic methods.

The disclosure does not teach how to achieve the instantly claimed property or assurance of particular results which would be obtained if certain direction were pursued producing an essentially protein free carbohydrate bacterial antigen which is a highly empirical process, yet the specification fails to teach the critical or key characteristics of the bacterial carbohydrate antigens; moreover, the specification needs to teach particular combination of reagents. There are an infinite number of combinations of

possible columns, gradients, gels, centrifugations, in combination with appropriate buffers of varying pH, salt, etc., however, the specification fails to supply an essentially protein-free carbohydrate antigen from any bacteria. In absence of further guidance from applicants as to how to purify the antigens to a degree which is an essentially protein-free carbohydrate antigen, and in view of the unpredictability and complexity in the art, it would require undue experimentation on the part of a skilled artisan to discover the key and critical characteristics of the bacteria which allow one skilled in the art to choose from the plethora of bacterial purification procedures in order to achieve an essentially protein-free carbohydrate antigen. The claims are further drawn to conducting an assay which ~~comprising~~ comprises detecting crude carbohydrate antigen of a species of bacteria by contacting the liquid sample with a detection agent which essentially comprises labeled purified antigen-specific antibodies, however the specification recites, at page 20 section C, Immunoassay procedures, require adding "reagent A", Tween 20, sodium azide, sodium ~~dodecyl~~ dodecyl sulfate in sodium citrate phosphate buffer to produce the crude carbohydrate antigen, however the instant claims fail to recite adding the appropriate reagents. Moreover, the specification does not appear to enable the use of any bacteria with the recited reagents especially when Legionella is extracted a different "reagent A" solution (tris base containing SB3-8, a zwitterionic detergent) See 09/458,998 page 9. Thus, it is unclear that one of skill in the art could follow these general guidelines and achieve purification of an essentially protein-free carbohydrate antigen.

Applicant asserts that the application does not suggest that a carbohydrate antigen characteristic of both a gram-negative and gram-positive bacterial species at the same time, and that the specification does not to target both simultaneously. Applicants also state that urine is known to have far more pronounced effect on breaking open cell walls of bacteria, however there is no requirement that sample be taken only from urine and thereby eliminate the need for other reagents. However, the instant claims fail to distinguish between detecting gram negative and positive bacteria by separate method steps. The broad and generic claims encompass detecting at least species or serogroup of any bacteria, thereby including detecting multiple species in the manner claimed. If applicant does not intend for the claims to encompass such the applicant should narrowly tailor the claims to only encompass what is taught and supported by the instant specification. Applicants statements that specific sample types perform extraction on some bacteria only bolsters the examiner's position that broad generic techniques cannot apply to all types of bacteria in any type of sample. Therefore applicants' arguments are not persuasive and the rejection is maintained.

It is noted that applicants' reference to the wet cell pellet is moot since the claims no longer recite such.

Applicants assert that the specification discloses detecting antigenic derivatives of lipoteichoic acids and teichoic acids, however the issue is what are the specific structures of the derivatives, not whether the language was used in the specification. Therefore applicants' comments that esters are the most obvious derivatives are not

persuasive since esters are not the only derivative. Moreover, there is no limitation of what can or cannot be a derivative. The specification provides no guidance as to what derivatives of either lipoteichoic acid or teichoic acid are and what structures can or cannot be encompassed by derivatives. The substitution of any derivative would not predictably result in a detectable crude antigen. The specification does not provide guidance on how to produce said derivatives from the crude antigen. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which derivatives of the acids will enable the detection of the crude antigen in the recited method. Accordingly, one of skill in the art would be required to perform undue experimentation to use derivatives of either lipoteichoic acid or teichoic acid to detect the crude antigen. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

The instant claims, 43-52, are not limited to the O-linked carbohydrate antigens, but rather to essentially free protein carbohydrate antigens. However application 09/139,720 teaches detailed preparation of antibodies specific to O-carbohydrate antibodies of *Legionella pneumophila*. The specification of 09/458,998 on page 4 at line 10-12 states that " applicants [redacted] developed a modified enzyme immunoassay ("EIA") using a coated tube in which *L. pneumophila* serogroup 1 raw polyclonal antibodies [redacted] have been purified according to the affinity purification procedure described and claimed in the parent application." See also page 5 paragraph 1 of the 09/458,998 specification. Therefore, the purified raw polyclonal antibodies and procedures disclosed in both

09/139,720 and 09/458,998 specifications are what are being used in the instant application when referring to Legionella. Therefore, the claims of the instant application need to claim the same O-carbohydrate antigens and purified raw polyclonal antibodies as described in the specifications. Claims 43-52 of the instant application fail to require the use of O-polysaccharide antigen sample or the use of purified raw polyclonal antibodies. Claims 43-52 of the instant application are not commensurate in scope with the examples taught in the specifications of 09/139,720 or 09/458,998. The 09/139,720 specification requires conjugation and coupling of the O-polysaccharide antigen to the chromatographic column and further requires affinity purification of the antibodies to the O-polysaccharide antigen. The O-polysaccharide antigen must be present to create the antigen specific *Legionella* antibodies. Thus purified raw polyclonal antibodies recognizing the O-carbohydrate antigen of *Legionella* will bind and detect the presence of *Legionella*. However, the claims of the instant application do not recite the essential use of the O-carbohydrate antigen or their purified raw polyclonal antibodies. Therefore, the claims do not include the limitations taught by the parent specification, thus they are not enabled.

Claims 36 and 45 recite esters of either lipoteichoic acid or teichoic acid, however there appears to be no support for the ester of either in the specification, thus the claims are not enabled for esters of either acid. The specification provides no guidance as to what esters of either lipoteichoic acid or teichoic acid can be produced. The claims broadly recite said esters, but fails to disclose the production of specific esters. Thus the recitation of esters of either lipoteichoic acid or teichoic acid is not

enabled by the specification. The substitution of any esters would not predictably result in a detectable crude antigen. The specification does not provide guidance on how to produce esters from the crude antigen. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which esters of the acid will enable the detection of the crude antigen in the recited method and device. Accordingly, one of skill in the art would be required to perform undue experimentation to use esters of either lipoteichoic acid or teichoic acid to detect the crude antigen. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Absent clear demonstration of the detection of any bacterial carbohydrate antigen, the purification and detection methods could not used in any well-established manner. In absence of further guidance from applicants, the skilled artisan would have to discover what the appropriate substrate is and the conditions under which each gram negative and/or gram-positive bacteria could be extracted. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for none routine experimentation demonstrates the specification is not enabled for the asserted use or well-established use for detection of bacterial carbohydrate antigens. Accordingly, the specification is not enabled for using the alleged method and device in any manner disclosed and the rejection is maintained.

7. The new matter rejection of claims 24, 33, 37, 42 and 46 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons already of record.

Claim 24 recites derivative of either lipoteichoic acid and teichoic acid however, there appears to be no support in the specification for the derivatives of either; claims 37 and 46 recites esters of either lipoteichoic acid and teichoic acid, however there appears to be no support for the ester of either in the specification. Claims 33 and 42 are drawn to detecting *Haemophilus influenzae* type b, however there appears to be no support in the specification for using the claimed purification steps to specifically purify Haemophilus antigen. Applicant has not addressed the rejection and has not pointed to support in the specification by page and line number.

8. Claims 22-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is unclear. Claim 22 (c) is unclear because it recites passing antibodies over the chromatographic affinity gel to produce purified carbohydrate specific antibodies, however it is unclear where the antibodies came from. There is no recitation by the claim as to making the antibodies, thus the antibodies must be obtained before they are passed through the column. Clarification is requested. Step (d) refers to conducting an assay, in a method to detect antigens, there are no assay steps being claimed. The claim is incomplete.

Step (d) of claim 22 refers to detecting the antigens which is counterpart to the purified antigen of step (c). It is unclear how the antigens are counterparts. Applicants' explanation of the antigens is unclear. It is unclear how the detection agent comprises labeled purified antigen-specific antibodies from step (c). At what point did the antibodies get labeled? The claim fails to recite a step wherein the antibodies can contact, bind and detect the antigen. The metes and bounds of the claim cannot be understood, since the claims fail to recite the necessary method steps.

Claim 22 (d) recites the limitation "labeled purified antigen-specific antibodies", however there is insufficient antecedent basis for this limitation in the claim. Also, it is suggested that the last word of claim 22 "hereof" be deleted from the claim.

9. Claim 24 recites derivative of either (lipoteichoic acid or teichoic acid). The specification is silent concerning a definition of what constitutes the metes and bounds of such derivatives of either lipoteichoic acid or teichoic acid. Therefore, the claim is unclear and indefinite as to what is encompassed by the phrase "derivative of either". It is unclear how to define the derivative when there appears to be no support in the specification for the derivatives of either. Thus the metes and bounds of the claim cannot be ascertained.

10. Claims 36 and 45 recite esters of either (lipoteichoic acid and teichoic acid) however this recitation makes the claim indefinite. The specification is silent concerning a definition of what constitutes the metes and bounds of such derivatives of either lipoteichoic acid or teichoic acid. Therefore, the claim is unclear and indefinite as to

what is encompassed by the phrase "derivative of either". It is unclear how to define the derivative when there appears to be no support in the specification for the derivatives of either. Thus the metes and bounds of the claim cannot be ascertained.

11. Claims 35-36 and 44-45 are incorrect. Gram-positive bacteria can be detected by their lipoteichoic acid, and teichoic acid, while lipopolycarbohydrate antigen can detect gram-negative bacteria. Claims 35 and 44 erroneously state that gram-positive bacteria can be detected with lipopolycarbohydrate antigen. Claims 36 and 45 erroneously state that gram-negative bacteria can be detected with lipoteichoic acid, and teichoic acid. Correction is required.

Incorporation By Reference

12. The incorporation of essential material in the specification by reference to another patent application is improper. The requirement for applicant is clear. An affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). US application 09/139,720 and 09/458,998 describe the purification of an essentially protein free lipo-carbohydrate antigen of bacteria of *Legionella* species, while 09/397,110 describes the purification proves to an essentially protein-free state of the C-polysaccharide cell wall antigen present in *S. pneumoniae* serotypes. Thus each reference is attempting to

incorporate essential purification procedures. The attempt to incorporate subject matter into this application by references to 09/139,720, 09/397,110 and 09/458,998 is improper because the incorporation by reference attempts to incorporate essential material. Applicant must execute an affidavit or declaration to overcome this improper incorporation.

Double Patenting

13. Applicants' statement concerning a terminal disclaimer is acknowledged. However the rejection will be maintained until such time.

The rejection of claims 22-32, 34-40, and 43-51 of this application conflict with claims 10-14 and 25-29 of Application No. 09/458,998 is maintained.

The provisional rejection of claims 22-23, and 25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-14 and 25-29 of copending Application No. 09/458,998 is maintained.

The provisional rejection of claims 22, 24, 26-32, 34-40, and 43-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-36, 41, 43-46, and 50-54 of copending Application No. 09/397,110 is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The rejection of claims 43-52 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., (US Patent 5,415,994) in view of Barthe (J. Clin. Micro. 1988) is maintained.

Applicant argues that there is no evidence that the prior art device was used to detect either *Legionella* or *Haemophilus*.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., detection either *Legionella* or *Haemophilus* are not recited in the rejected claims. The claims are drawn to a device and its components. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Imrich et al. (US Patent 5,415,994), teach devices, methods and kits for detecting analytes in biological sample where prior to detection, extraction can occur. It would have been prima facie obvious to modify the immunochromatographic device for the detection of an antigen of a species of bacteria, which comprises a first and second zone and method for detecting the crude antigen as taught by Imrich et al., to include the monoclonal antibody of Barthe et al., because Barthe et al., antibody recognizes several crude carbohydrate antigens from *Legionella*. One would have a reasonable expectation of success by incorporating an antibody which recognizes a common epitope found on Legionella, into the device and method of Imrich who already teaches

using the antibodies to bind and label the bacterial antigens to detect their presence. Moreover, no more then routine skill would have been required to use an alternative yet functionally equivalent antibody in the labeling and capturing technique of Imrich et al., since only the expected results would have been obtained; thus the use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the monoclonal antibodies ability to recognize several *Legionella* serogroups.

Claims 42-46 are drawn to an ICT device, while claims 48-52 are drawn to a method of detection using the device, however the claims recite the use of antigen-specific antibodies. The claims are drawn to a product by process, however the process for creating an essentially free protein carbohydrate antigen do not ~~create~~ provide for a materially different antibody. The antibody of Barthe et al., will also bind to the crude carbohydrate antigen. Thus, absent evidence to the contrary, the antibody of Barthe et al., meets the limitations of the claimed device, by being capable of binding to crude carbohydrate antigens. Applicants' claims are drawn to device, thus the source of immunoglobulins also known as antibodies, do not provide a structural difference between the device of Imrich et al., in view of Barth et al. Moreover, there are no structural differences between the claimed antibody and device and the antibody and device of the recited prior art. A structural difference needs to exist in order to patentably distinguish the claimed invention from the prior art; the prior art antibody and device are capable of performing just like the instantly claimed device, thus they meet the claimed limitations.

Therefore, the rejection is maintained.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
March 17, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600